

## EXHIBIT 288

## **Purdue Pharma L.P.**

SUBJECT:

ABUSE AND DIVERSION DETECTION

SOP NO.:

LAW DEPARTMENT SOP 1.7.1

EFFECTIVE DATE:

SEPTEMBER 2015

SUPERSEDES:

JUNE 2007

### **Purpose**

The Abuse and Diversion Detection Program ("ADD Program") is designed to ensure that interactions with Prescribers or Pharmacists, that reveal observations or circumstances that suggest potential concerns, generate appropriate review and follow up. The program's objective is to preclude promotion of Purdue's opioid products in circumstances where there is a concern about potential abuse or diversion related to a particular Prescriber, Pharmacist, his/her patients, or opioid products.

This policy establishes an internal procedure for implementing the ADD Program ("ADD Policy"). The procedure provides specific examples of observations and circumstances that warrant review and follow up through the submission of an ADD Report (as defined below).

### **Applicability**

This program applies to:

- all members of Purdue's field sales organization, medical science liaisons and other Purdue employees and contract or third party sales representatives who contact practicing Prescribers or Pharmacists (as defined below) in person or by telephone for the purpose of promoting a Purdue opioid product; and
- all field-based employees who contact managed care organizations.

The individuals to whom this ADD Policy applies are referred to as "ADD Covered Persons." For purposes of this ADD Policy, Prescribers and Pharmacists are persons duly licensed under relevant federal and/or state law to prescribe or dispense opioid products.

This program applies to Purdue Pharma L.P. and associated U.S. Companies that manufacture, sell, distribute and/or promote Purdue's branded opioid products (the "Company" or "Purdue").

### **Observations and Activities Requiring an ADD Report**

In the event that an ADD Covered Person learns of or observes any of the situations described below, such activities or observations must be reported promptly in accordance with the procedures outlined below ("ADD Report"):

1. An apparent pattern of an excessive number of patients for the practice type (for example: on a consistent basis, a long line of patients waiting to get prescriptions; a waiting room filled to capacity or standing room only; patient contact with a prescriber that is exceedingly brief or non-existent).
2. An atypical pattern of prescribing techniques or locations (for example: repeated prescribing from an automobile; repeated prescribing at atypical times, such as after usual office hours when the health care professional is not on call).
3. Information from a highly credible source or several sources (for example: pharmacists, law enforcement, or others) that a Prescriber or Pharmacist or his/her patients are diverting medication.

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4. A Prescriber or Pharmacist who has a disproportionate number of patients who pay cash for office visits and dispensed medication. (Note: This is not to be confused with co-pay payments of a nominal amount).
5. A Prescriber or Pharmacist with a sudden unexplained change in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or the practice type.
6. An allegation that individuals from a particular Prescriber or Pharmacist's practice have overdosed.
7. A credible allegation that a Prescriber or Pharmacist, staff or patient has abused or is actively abusing substances.
8. A Prescriber or Pharmacist's practice where unauthorized individuals are signing prescriptions or dispensing controlled substances.
9. A Prescriber or Pharmacist's practice with large numbers of patients who travel significant distances, for example across state lines, to obtain and/or fill their prescriptions without a rational explanation.
10. A Prescriber or Pharmacist's practice where there are reports that patients make frequent early requests for new prescriptions significantly in advance of the time the initial prescription would normally have been completed.
11. A credible allegation that a Prescriber or Pharmacist is under active investigation by any law enforcement or regulatory authority, including medical boards.
12. A Prescriber or Pharmacist who moves his or her practice from one state to another on more than one occasion within a couple of years without rational explanation.
13. A Prescriber with an atypical patient population from that customarily observed in such an office based on its location and other attendant circumstances. For example, a disproportionate number of younger patients for the nature of the practice.
14. A Prescriber lacks understanding about the risks associated with prescribing opioids. For example, a Prescriber who states that he or she does not have basic information about the risk of addiction associated with opioid therapy.
15. Facts that suggest that the Prescriber's patients are seeking opioids for misuse and abuse, including but not limited to facts that suggest that a Prescriber has failed to comply with his or her state's prescription monitoring program. For example, failure to comply with New York's Internet System for Tracking Over-Prescribing/Prescription Monitoring Program (I-STOP/PMP).

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**Responsibility and Procedure for Completing and Submitting an ADD Report**

The ADD Report must be completed promptly, ideally within 48 hours of when an ADD Covered Person learns of a circumstance or makes an observation that may be indicative of potential abuse or diversion. The ADD Report must be sent either through: (i) the call note functionality in Phoenix or (ii) by email to Drug Safety and Pharmacovigilance ("DSP") using the ADD Form. The ADD Form may be found on the Compliance tab in the Phoenix Desktop Library or on the Policies and Standards page on the Purdue intranet (the "ADD Form").

The ADD Covered Person filing the ADD Report should not discuss his or her observations or the ADD Report with anyone other than his or her manager and persons designated by the Law Department. Once an ADD Report has been filed, notice will be provided that an internal inquiry is pending. While pending, no calls should be made on the Prescriber or Pharmacist that is the subject of the ADD Report until and unless a member of the Law Department provides written notification permitting such contact.

**Law Department Internal Inquiry**

Completed ADD Reports will be delivered to an email mailbox accessed by DSP and forwarded to the Law Department for review, evaluation, and follow up. A member or designee of the Law Department will conduct a review and appropriate follow up based on the ADD Report.

At the conclusion of the Law Department's internal inquiry, individuals with responsibility for calling on the Prescriber or Pharmacist will be informed, in writing, with a copy to appropriate management, whether ADD Covered Persons may continue to promote Purdue opioid products to the particular Prescriber or Pharmacist who is the subject of the ADD Report.

If the Law Department determines that ADD Covered Persons should not call on a Prescriber or Pharmacist ("no call"), a copy of that notification also will be sent to Sales Operations. In the event that an internal inquiry involves a Prescriber or Pharmacist upon whom a contract or third party sales representative may call, those individuals also will be notified. Prescribers or Pharmacists with "no call" status will be denoted as such in Phoenix.

**Continuing Obligations**

Sales calls should not be scheduled or made on Prescribers or Pharmacists who are designated as "no call" in Phoenix or who have an ADD inquiry pending as noted in Phoenix ("under review"). Each week, prior to making sales calls, all ADD Covered Persons shall create a call plan. Prior to making sales calls, ADD Covered Persons shall check whether the Prescribers or Pharmacists that they plan to call on that week have a "no call" or "under review" status in Phoenix. Interactions with a Prescriber or Pharmacist designated as either "no call" or "under review" will trigger an email notification to Sales management and the Law Department for review to determine if such interaction is in violation of this ADD Policy.

If during a call on a Prescriber or Pharmacist, an ADD Covered Person learns of concerns about compliance or potential abuse issues involving that Prescriber or Pharmacist, the concern must be noted in detail in the call note and the ADD Covered Person should use the call note functionality in Phoenix to submit an ADD Report. If compliance or potential abuse issues are raised during sales calls to Prescribers or Pharmacists about other Prescribers or Pharmacists, a call note must be generated for the Prescriber or Pharmacist who provided the information to

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record such interaction and the ADD Covered Person should submit an ADD Report using the ADD Form rather than the Phoenix functionality.

All ADD Covered Persons shall be required to complete training on this ADD Policy annually.

**Compliance Review of Call Notes**

The Corporate Compliance Department shall audit and review call notes to evaluate compliance with this ADD Policy. Should Compliance determine that an ADD Report may have been required, the call notes will be referred to the Law Department for further review.

**Incentive Compensation Impact**

If the Law Department determines that a Prescriber or Pharmacist is a "no call", no sales incentive (bonus) shall be earned from prescriptions written by such Prescriber or Pharmacist for sales generated after such determination. Specifically, sales bonus will be calculated after the removal of the sales and sales history attributed to that Prescriber. Please refer to Field Sales Bonus SOP 2.3 for additional information.

**Violations of this ADD Policy**

Violations of this ADD Policy may result in disciplinary action including but not limited to written warning, probation, bonus ineligibility, or termination of employment. If the Law Department determines that an ADD Covered Person failed to file an ADD Report regarding a Prescriber or Pharmacist and the Company determines that individual knew or should have known that the Prescriber or Pharmacist was engaged in conduct covered by this ADD Policy, that will be considered a violation of this ADD Policy and will result in an ADD Covered Person being deemed ineligible for his or her quarterly bonus.

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- NY ADDENDUM

EFFECTIVE DATE:

LAW DEPARTMENT SOP 1.7.1  
SEPTEMBER 2015

**Purpose**

This New York Addendum ("NY Addendum") to the ADD Policy is designed to ensure compliance with the New York specific requirements contained in the Assurance of Discontinuance ("AOD") entered into with the New York State Attorney General effective August 19, 2015.

**Applicability**

This NY Addendum applies to any ADD Covered Persons who have contact with practicing Prescribers or Pharmacists in New York State.

**Continuing Obligations**

Beginning in January 2016, and annually thereafter, on the first call on Prescribers or Pharmacists in New York, ADD Covered Persons must inquire whether the Prescriber or Pharmacist has completed a training program regarding the appropriate prescribing of opioids the content of which is compliant with the FDA's Risk Evaluation Mitigation Strategy ("REMS") for Extended Release/Long-Acting Opioids. If the Prescriber or Pharmacist indicates that such training has not been completed, the ADD Covered Person shall provide the Prescriber or Pharmacist with approved REMS materials.

Should a Prescriber or Pharmacist in New York request information regarding addiction treatment, the ADD Covered Person shall provide the Prescriber or Pharmacist with approved resources or refer the Prescriber or Pharmacist to Medical Services.

**Violation of Policy**

Failure to comply with the obligations set forth in this NY Addendum may result in disciplinary action as set forth in the ADD Policy.